

The Design of the PlasmaJet® Thermal Plasma System and Its Application in Surgery

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ABSTRACT: While cold-plasma discharges may have applications such as disinfection and wound treatment, they have insufficient power to produce a surgical effect. Here we discuss the use of a multi-electrode array designed to deliver an arc discharge with a much higher power density and the construction of the PlasmaJet® system, which uses low gas flow and can deliver thermal plasma with the ability to cut and coagulate all tissues. In contrast to conventional electrosurgery systems that employ an external electrical current, the PlasmaJet system, with an electrically neutral energy source, provides a safer alternative. The results of tissue studies are presented, confirming that this thermal plasma has the ability to cut tissue precisely and with simultaneous coagulation yet acts quickly, with minimal damage to underlying and adjacent tissue. The clinical applications of this new energy source for surgery are discussed, and the first clinical experience suggests that this thermal plasma system has valuable applications in surgery.

KEY WORDS: thermal plasma, plasma surgery, PlasmaJet, tissue studies, clinical experience, plasma medicine

I. INTRODUCTION

The majority of recent papers in the field of plasma medicine have described the potential clinical applications of low-temperature or so-called “cold” plasmas, usually generated by a dielectric barrier discharge. These applications include disinfection and wound treatment, but non-thermal plasmas have low power density and insufficient power to produce a surgical effect.

The design of a thermal plasma system for surgical use must to consider the surgeon’s real needs. These can be summarized as the ability to precisely and effectively cut and remove all types of tissue with simultaneous coagulation and minimal damage to surrounding structures. The ability to operate with the highest levels of safety is another evident requirement. For many years, successful minimally invasive surgery has relied upon powered surgical devices to achieve relatively bloodless cutting, ablation, and coagulation of tissues. The most widely used technologies have been electrosurgery and the CO₂ laser, with ultrasonic and powered vessel-sealing devices augmenting the

armamentarium of the laparoscopic surgeon. However, each of these technologies has its limitations, and none fully meet the surgeon's needs.

Herein, we report on the development of a device producing a pure thermal plasma flow that provides a new energy source for use in surgery. With significant advantages of safety and minimal damage to adjacent and underlying tissues, plasma surgery has much to offer the surgeon. This article describes this new thermal plasma technology, compares its capability to conventionally powered surgical devices, and describes both its effects on tissue and some of its clinical applications in surgery.

II. PLASMA DEVICES USED IN SURGERY

A. Electrosurgery Systems That Use Plasma

As radiofrequency electrosurgery devices have been further developed to overcome the inherent limitations of this nearly 90-year-old technology, several devices have emerged that use the word plasma in their name or in the description of their mechanism of operation. However, it is questionable whether these electrosurgery systems derive any significant clinical effect through the use of plasma. In argon-enhanced electrosurgery using devices such as the Argon Beam Coagulator produced by the ConMed Corporation and the APC Argon Plasma Coagulator produced by Erbe GmbH, a monopolar electrosurgery device passes a stream of electrosurgical sparks through a flow of argon gas. The argon gas stream may well help to remove liquid blood from a tissue surface and facilitate the electrosurgical coagulation effect. However, while a small amount of the argon employed may ionize to form plasma, this has a very low power density, and insufficient thermal energy to provide any significant surgical effect; and the essential agent of the surgical action remains the electrosurgical flow of current through the tissue.

Several additional recent electrosurgical devices operate in a liquid field and can be collectively described to facilitate "fluid-coupled electrosurgery." Thus, the so-called PlasmaKinetic® technology employed in the Olympus (Gyrus ACMI) Plasma-Knife® and related products, and the ArthroCare Coblation® technology are examples of devices that refer to the generation of plasma when describing their method of operation, but in practice they use radio-frequency electrosurgery via specially designed bipolar electrode systems. While these may well generate low-temperature plasma within the tiny gas bubbles formed in the fluid on the surface of their electrodes,¹ the basic operating principle remains that of electrosurgery. Similarly, the Medtronic (Peak Surgical) PlasmaBlade® may also generate low-temperature plasma at the interface of the handpiece blade with the tissue in which it is used; but it is more likely that the rapid pulses of radiofrequency energy at high voltage create the surgical effect. In all electrosurgical devices that generate non-thermal plasma, it is used mainly to create a conductive pathway for electrical current, and it is unlikely that the plasma itself at the low temperature at which it is employed has a significant surgical influence beyond that of mediation of the electrosurgical effect.

Two devices are available that use a radiofrequency electrosurgery source to produce a relatively low power helium plasma by corona discharge that can be used to coagulate tissue. The Helica Thermal Coagulator has been used mainly in the United Kingdom in the surgical management of endometriosis, while the Bovie J-Plasma has recently received FDA approval for use as a coagulation device and has been combined with a retractable blade to provide cutting during conventional electrosurgery.

B. Pure Thermal Plasma

The origins of a pure thermal plasma with the ability to both cut and coagulate tissue lie in the early studies by Glover et al. at the University of Indiana in the mid 1970s. Glover and his team described the first plasma scalpel^{2,3} and compared it to the use of the steel scalpel and electrosurgery. Although effective as a surgical tool, the relatively simple, two-electrode handpiece device involved a relatively high gas flow. In early pre-clinical and clinical use, there was evidence of argon gas in the circulation with the concomitant risk of gas embolism. This may well have hindered its subsequent development, and no commercially available system arose from this early work.

In 1998, Shekhter et al. described the application of the Plason system.⁴ This system employs a DC arc and generates plasma using air generated by a built-in microcompressor passing through a liquid-cooled cathode, intra-electrode insert, and anode. The Plason system can operate in two modes. In “cold mode” the plasma temperature is maintained at 20–40° using a circulating liquid-cooling system and provides plasma flow containing nitric oxide, which has clinical applications in the stimulation of tissue regeneration and wound healing. However, in “hot mode” the thermal air plasma has been used for coagulation and sterilization of wound surface as well as the destruction and dissection of biological tissues.⁵

In the mid 1990s, Nikolay Suslov invented a multi-electrode system that generated plasma with a higher power density using a very low level of current.⁶ This design used a low-level DC current to generate a spectrally pure plasma flow in a small electrode group, which subsequently facilitated the design of small-diameter handpieces capable of generating a high power density of plasma flow using a very low argon flow, typically 0.2–0.6 L min⁻¹. This approach has been developed further during the last decade to create the PlasmaJet® system.

III. THE DESIGN OF THE PLASMAJET® SYSTEM

A. Multiple Electrode Array and Surgical Handpiece

The PlasmaJet® system (Plasma Surgical, Inc., Roswell, Georgia, USA) is arguably the only pure-plasma surgery device available today that has regulatory approval for use in North America and Europe, because the sole energy source used is the thermal plasma. This device does not employ an electrosurgical approach; it introduces a new surgical technology in the form of a pure thermal plasma flow which facilitates cutting, coagu-

lation, and ablation of tissue. This technology provides a unique and novel approach to producing these tissue effects, offering a series of advantages over electrosurgery, argon-beam coagulation, and the CO₂ laser.

The creation of thermal plasma that has sufficient power for a surgical effect requires an arc discharge in a device designed to deliver a high power density in the region of 1–5 kW mm⁻³. In this type of thermal plasma, the combined energy of all particles within the plasma (i.e., ions, electrons, and a small number of atoms) can achieve a plasma temperature in the region of 10,000–20,000°K. Because this plasma has an extremely high power density, it is capable of delivering a surgically useful power range of 20–200W, but at a very low argon gas flow of only 0.2–0.6 L min⁻¹, the plasma flow is so low that the overall thermal effect on tissue is limited. The use of a high temperature and low gas flow in the thermal plasma employed in the PlasmaJet system also reduces the formation of potentially harmful chemical species such as nitrogen dioxide and ozone. The role of reactive chemical species in plasma is well established,⁵ but in the thermal plasma of the PlasmaJet system in typical use, these remain within safe environmental limits.

The PlasmaJet system uses a low DC current and voltage applied between a series of internal electrodes to produce highly energetic pure argon plasma that on emission from the tip of the handpiece carries no external electrical current. Fig. 1 illustrates the multiple electrode array including a tungsten cathode, a copper alloy anode, and a series of intermediate isolated electrodes. Key elements of the handpiece tip design include integral cooling and electrode-group geometry that minimizes the contact between the plasma and the electrode surface. These combine to allow the formation of very hot plasma without the risk of melting of the electrodes. Spectroscopic studies confirm that the plasma produced by the PlasmaJet system contains no detectable electrode materials.

Fig. 2 illustrates the plasma jet emerging from the titanium-plated tip of the handpiece. When the emerging plasma comes into contact with tissue, it rapidly gives up its energy in three useful forms: (1) as light that is useful for illuminating the surgical field in laparoscopic procedures, (2) as heat that results in coagulation of bleeding surfaces, and (3) as kinetic energy, which is harnessed to cut and ablate tissue. The kinetic energy produced by the device first removes blood and liquids from the tissue surface. This is

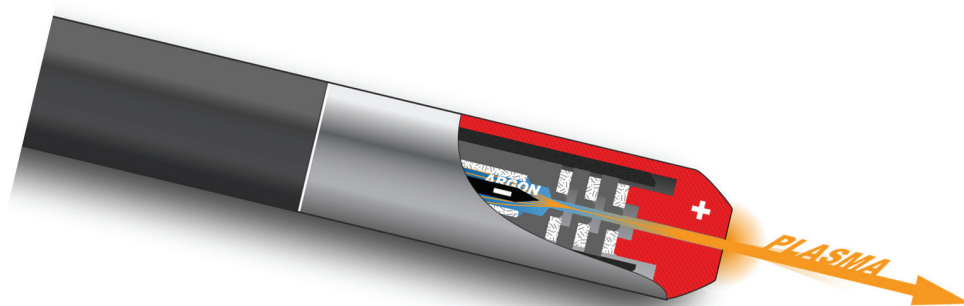


FIG. 1: Multiple electrode array

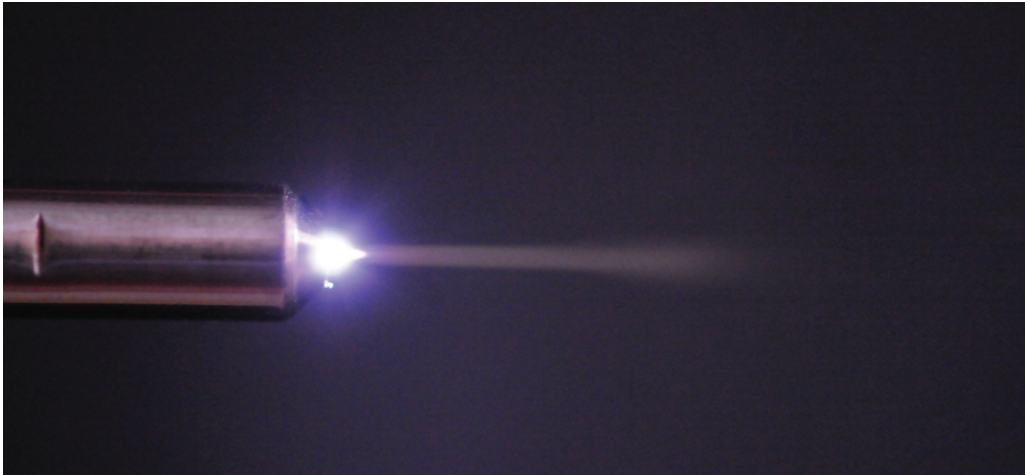


FIG. 2: The thermal plasma emitted from the tip of the PlasmaJet handpiece

followed by the transfer of thermal energy to the tissue, resulting in the formation of a thin and flexible yet complete sealing layer. The multiple electrode array is housed in the tip of a single-use disposable surgical handpiece (Fig. 3) that features a 5-mm diameter stem and is made available in 7 cm, 12 cm, and 28 cm lengths for use in open and laparoscopic surgery.

B. The PlasmaJet Console

The PlasmaJet console illustrated in Fig. 4 provides an initial ignition pulse of up to 3kV followed by a DC voltage in the region of 30V to maintain the plasma flow. The console also provides control electronics for the user interface, uses a mass flow controller to provide gas-flow regulation, and a circulating coolant to maintain the handpiece tip at a low temperature. The console is mounted on a floor-standing trolley that contains the argon gas tank within with a small, movable base for use in the operating room. The system is IEC 60601-1, IEC 60601-1-2, and ETL approved; FDA cleared; CE marked in Europe; and licensed by Health Canada.

C. Thermal Plasma Properties and Effects

The use of pure thermal plasma as used in the PlasmaJet system offers several benefits for use in surgery over the use of an electrosurgical technique or a CO₂ laser. The pure plasma produced by the PlasmaJet system carries no external electrical current. No ground pad is required, and there is no risk of evoked potentials in nearby nerves or of capacitive coupling or alternate site burns in a laparoscopic setting. Compared to the CO₂ laser, the PlasmaJet offers a similar advantage of precise cutting and ablation of tissue, but it has greater coagulation capability, and there is no risk of overshoot. Unlike



FIG. 3: PlasmaJet handpiece

the laser in which there is little loss of energy with distance, in the PlasmaJet system the energy that is sufficiently high close to the tip of the handpiece to be able to cut tissue falls off exponentially with distance to give the surgeon control over the surgical effect. At greater distance from the tissue the effect lessens to allow coagulation of tissue, and at a distance of approximately 3 cm there is little effect (Fig. 5). Fig. 5 shows the wider zone of coagulation power that surrounds the smaller central zone of cutting and ablation capability. Compared to laser surgery, with the PlasmaJet system there is no risk of reflection of the energy beam from other instruments; maintenance cost is minimal; and no investment is required for staff certification.

The PlasmaJet system is unique as a surgical energy source capable of cutting and coagulating all tissues, including bone; a capability that electrosurgery systems do not have because bone is non-conductive to the flow of electrical current on which this conventional technology depends. However, the major benefit is the minimal damage to the underlying and adjacent tissues. In the most recent version of the PlasmaJet system, the precision of the cut has been improved further, and the coagulation capability has been increased by rapidly pulsing the plasma between two preset energy levels in a so-called “Ultra” mode of operation.



FIG. 4: PlasmaJet console and service trolley

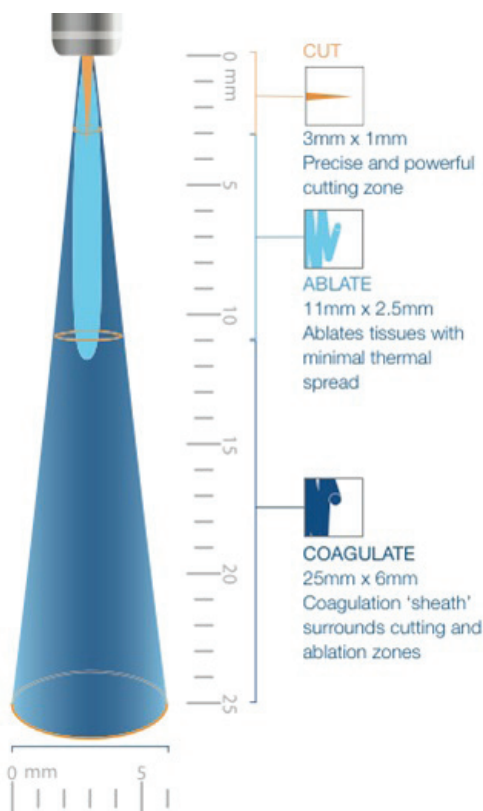


FIG. 5: The zones of action in the PlasmaJet stream

IV. THE EFFECT OF THERMAL PLASMA ON TISSUE

The results of a series of preclinical studies⁷⁻⁹ have shown that the PlasmaJet system produces a similar effect when applied to a variety of different tissues. The maximum depth of tissue necrosis in these studies was approximately 2.0 mm for dense and vascular tissues such as the liver, spleen, and kidney, and in many cases the typical depth of tissue damage was much less, at approximately 0.2–0.5 mm. The effect of the PlasmaJet system was similar in all tissues studied. Fig. 6 illustrates a typical effect of plasma energy on tissue. Beneath a very thin layer of carbonized tissue, a desiccated or spongy layer of tissue can be observed, and beneath this lies a more compact layer of coagulated tissue. The overall effect is the formation of a thin, yet complete and flexible sealing layer. In this work, we noted that a maximum depth of tissue necrosis was approached after only 5 seconds with the PlasmaJet system. Prolonged exposure (more than is necessary to achieve coagulation) led to ablation of tissue without a significant increase in the depth of necrosis in the remaining tissue (Fig. 7).

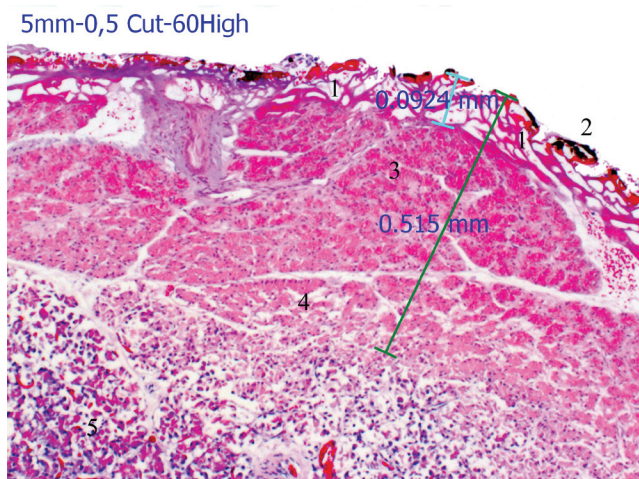


FIG. 6: The effect of plasma energy on pancreatic tissue

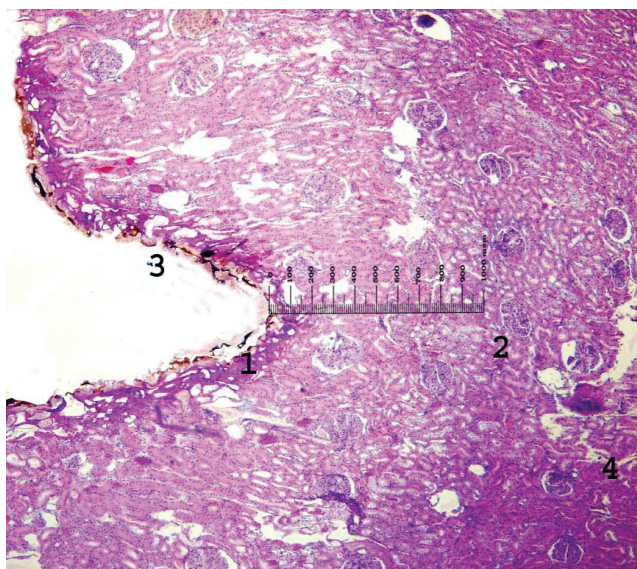


FIG. 7: Tissue effect of the PlasmaJet when applied for a longer period to kidney tissue

Comparing the effects of the PlasmaJet system and conventional electrosurgery techniques,⁷ both argon-beam coagulation and fluid-coupled electrosurgery produced a greater depth of tissue necrosis when compared to the PlasmaJet system (Fig. 8). The use of argon beam coagulation resulted in the formation of a deeper coagulated layer, which was also punctuated by holes caused by sparks that penetrated deep into the underlying tissues (Fig. 9).

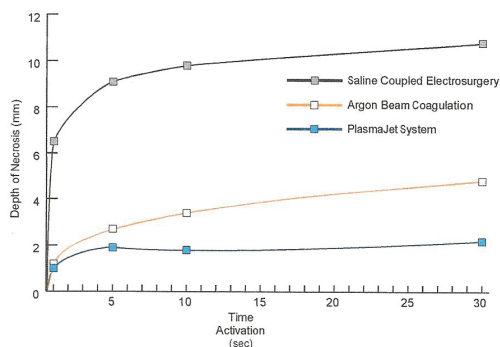


FIG. 8: Graph comparing tissue effect over time

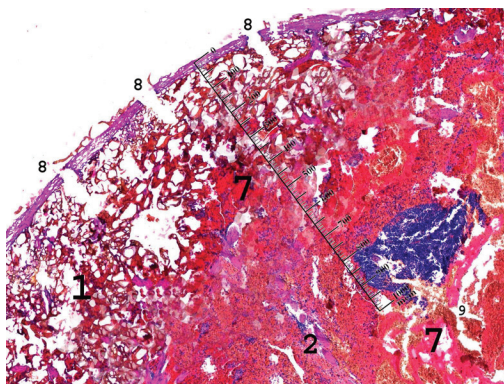


FIG. 9: Tissue effect of argon beam coagulation on the spleen

Post-operative tissue effects and healing have been compared for the PlasmaJet system versus other technologies at up to 21 days following surgery.^{8,9} All of the tissues demonstrated healing over time, regardless of the technology utilized. For tissue treated with the PlasmaJet system, the scar was actively reconstructed, total scar mass diminished, and a simple linear scar remained without any negative effect on deeper underlying tissues. Detailed histological studies⁹ have also demonstrated that on the boundary of the necrotic tissue there is a broad area of cell-rich granulation tissue with distinct immunohistochemically positive proliferative vessels. A clear demarcation between the thin sealing layer and the vital tissue was observed, and no evidence of hemorrhage occurring after treatment with the PlasmaJet system was recorded.

V. CLINICAL EXPERIENCE WITH PLASMA SURGERY

In addition to these preclinical studies, several groups have now reported results associated with the clinical use of the PlasmaJet system in surgery.^{10–21} Several of these studies confirm the tissue effects and the minimal depth of penetration associated with the use of the PlasmaJet system. Sonoda et al.¹⁰ studied *ex vivo* ovarian and peritoneal tumor samples following use of the PlasmaJet system and reported that lateral thermal damage associated with the use of the device was minimal with a mean depth of necrosis of 0.13 mm (range: 0.08–0.2 mm). Deb et al. reported on the depth of tissue damage with the PlasmaJet system based on *ex vivo* gynecological samples and confirmation via *in vivo* evaluation.¹¹ They reported a mean depth of tissue damage of 0.63 mm in the uterus, ovary, and fallopian tube. In a separate study, Madhuri et al. conducted histopathological examinations of *ex vivo* samples of omentum bearing epithelial ovarian carcinoma and reported a mean depth of tissue damage of 0.15 mm (range: 0.07–0.4 mm) and a mean lateral thermal spread of 0.22 mm associated with the use of the PlasmaJet system.¹²

Nezhat et al. were the first to report the use of the PlasmaJet system in the laparoscopic management of endometriosis.¹³ Studies followed in the United Kingdom,¹⁴ with

both groups confirming the ability of the PlasmaJet system to either cut or ablate endometriosis lesions safely, with minimal damage to the underlying tissue. In studies focusing on the use of plasma energy in the management of ovarian endometrioma, Roman et al. reported on the benefits of sparing in this vital tissue as a result of treatment with the PlasmaJet system.^{15–17} In these studies, this group confirmed that the management of endometrioma using the PlasmaJet system results in minimal loss of viable ovarian tissue and enhanced fertility.

Other experience in laparoscopic gynecology includes the use of the PlasmaJet handpiece held at a greater distance from tissue to reduce the distension of vessels to treat pelvic congestion, and its use to cut the vaginal cuff in a hysterectomy procedure. In the latter case, the minimal damage to the cut surface of the vagina reduces the subsequent risk of dehiscence of the suture line. The PlasmaJet system has been used effectively to remove secondary tumor deposits from the peritoneal cavity in gynecological oncology cases, where the minimal damage to the underlying tissue allows tumor deposits to be removed safely from the sensitive structures such as the bowel and the diaphragm.¹⁴ Uses in open gynecological surgery include its use in the removal of malignant tumors from the vulva.¹⁸

The PlasmaJet system has been used in other surgical areas, including hepatic surgery¹⁹ and plastic surgery.^{20,21} The company's documented surgical experience of almost 1500 cases includes cases in which thoracic, orthopedic, and spinal surgeries were performed.

VI. CONCLUSIONS

The PlasmaJet system introduces a new energy source for surgical use, a thermal plasma that is safe and effective in cutting, ablating, and coagulating tissue. Handpieces featuring a multi-electrode group have been designed such that this type of plasma energy has minimal effects on underlying and adjacent tissue. With no external electrical current, the technology improves on electrosurgery by reducing tissue damage, providing the ability to cut and coagulate all tissues (including bone) and eliminating the risks of evoked potentials, capacitive coupling, and alternate site burns. As a precise yet gentle means of removing tissue and leaving a thin and flexible sealing layer, the PlasmaJet system has demonstrated valuable benefits in gynecological surgery and surgical oncology and has potential applications in many other surgical areas, including general surgery, plastic surgery, thoracic surgery, spinal surgery, and orthopedic surgery.

REFERENCES

1. Stalder KR, Wolowszko J. Electrical discharges in conducting liquids: plasma-mediated electrosurgical systems. In: Laroussi M, Kong MG, Morfill G, Stolz W, editors. *Plasma Medicine*. Cambridge University Press; 2012. p. 261–93.
2. Link WJ, Incropera FP, Glover JL. A plasma scalpel—comparison of tissue damage and wound healing with electrosurgical and steel scalpels. *Arch Surg*. 1976; 111:392–7.

3. Glover JL, Bendick PJ, Link WJ, Plunkett RJ. The plasma scalpel—a new thermal knife. *Laser Surg Med.* 1982; 2:101–6.
4. Shekhter AB, Kabisov RK, Pekshev AV, Kozlov NP, Perov L. Experimental and clinical validation of plasmadynamic therapy of wounds with nitric oxide. *Bull Exp Biol Med.* 1998;126:829–34.
5. Fridman G, Friedman G, Gutsol A, Shekhter AB, Vasilets G, Fridman A. Applied plasma medicine. *Plasma Process. Polym.* 2008;5:503–55.
6. Suslov N, inventor; Plasma Surgical Investments Ltd., assignee. Device to stop bleeding in living human and animal tissue. United States Patent No. 5,843,079 1998.
7. Parhomenko Y, Tartynski S, Kachikin A. The effect of the PlasmaJet when used for coagulation on a range of different tissues and comparison with the effects of argon enhanced electrosurgery and fluid coupled electrosurgery. Moscow: Institute of Human Morphology at the Russian Academy of Science; 2005.
8. Suslov N, Tartynski S, Kachikin A. The depth of injury created in a series of tissues by the cutting and coagulation properties of the PlasmaJet system. Sweden: University of Gothenburg; 2008.
9. Drecoll E, Höffler H. Effects of Plasma Jet coagulation on different tissues. Munich: Insitut für Allgemeine Pathologie und Pathologische Anatomie, Technische Universität München; 2010.
10. Sonoda Y, Olvera N, Chi DS, Brown CL, Abu-Rustum NR, Levine DA. Pathologic analysis of *ex vivo* plasma energy tumor destruction in patients with ovarian or peritoneal cancer. *Int J Gynecol Cancer.* 2010;20:1326–30.
11. Deb S, Deen S, Ashford KS, Harwood A, Newman C, Powell MC. Histological quantification of the tissue damage caused by PlasmaJet coagulator, *Gynecol Surg.* 2010; 7:441–6.
12. Madhuri TK, Butler-Manuel SA, Tailor A, Haagsma B. Pathologic analysis of tumour destruction with neutral plasma in epithelial ovarian carcinoma. 17th International Congress ESGO, Milan, Italy, September 2011.
13. Nezhat C, Kho KA, Morozov V. Use of neutral argon plasma in the laparoscopic treatment of endometriosis. *JSLs.* 2009;13:479–83.
14. Madhuri TK, Papatheodorou D, Tailor A, Sutton C, Butler-Manuel S. First clinical experience of argon neutral plasma energy in gynaecological surgery in the UK. *Gynecol Surg.* 2010;7:423–5.
15. Roman H, Pura I, Tarta O, Mokdad C, Auber M, Bourdel N, Marpeau L, Sabourin JC. Vaporization of ovarian endometrioma using plasma energy: histologic findings of a pilot study. *Fertil Steril.* 2011;95:1853–6.
16. Auber M, Bourdel N, Mokdad C, Martin C, Diguët A, Marpeau L, Roman H. Ultra-sound ovarian assessments after endometrioma ablation using plasma energy. *Fertil Steril.* 2011;95:2621–4.
17. Roman H, Auber M, Mokdad C, Martin C, Marpeu, L and Bourdel N, Ovarian endometrioma ablation using plasma energy versus cystectomy: a step toward better preservation of the ovarian parenchyma in women wishing to conceive. *Fertil Steril.* 2011;96:1396–400.
18. Madhuri TK, Tailor A, Butler-Manuel S. Use of neutral plasma coagulation in groin node dissection for vulvar malignancy: a novel technique. *Cancer Manag Res.* 2011;3:253–5.
19. Gugenheim J, Bredt LC, Iannelli A. A randomized controlled trial comparing fibrin glue and PlasmaJet on the raw surface of the liver after hepatic resection. *Hepatogastroenterology* 2011;58:922–5.

20. Iannelli A, Bafghi AR, Patrono D, Sautot-Vial N, Gugenheim J. Use of the PlasmaJet system in patients undergoing abdominal lipectomy following massive weight loss resulting from bariatric surgery: early experience. *Obes Surg.* 2006;16:1504–7.
21. Iannelli A, Schneck AS, Gugenheim J. Use of the PlasmaJet system in patients undergoing abdominal lipectomy following massive weight loss; a randomized controlled trial. *Obes Surg.* 2010;20:1442–7.